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(54) **Quick water-dissolving film containing cosmetic, aromatic, pharmaceutical or food substances and process for making the same**

(57) Film with high solubility in water, comprising a starch, a cellulose and a cosmetic, aromatic, pharmaceutical and/or food substance in a quantity exceeding 10% on the total film weight.

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moving the film from the support and die-cutting it to the required size.

[0012] To obtain the aforescribed product, numerous tests have shown that at least one of the following elements must be used:

a) at least one low molecular weight starch of high amylopectin content. The starch can be selected from those obtained from maize, wheat, potato, rice, soya, tapioca, etc. This starch must be present between a minimum of 20% and a maximum of 80% by weight on the final film composition.

b) at least one cellulose compatible with said starch, preferably chosen from the following substances: hydroxypropylcellulose, hydroxypropylmethylcellulose, hydroxyethylcellulose, carboxymethylcellulose. These polymers and celluloses must be present in the finished product (film) from a minimum of 15% to a maximum of 70% by weight.

[0013] Other ingredients the presence of which is preferred in producing the film are polysorbate 80, sorbitol, glycerol mono oleate, carrageenan, soya lecithin, colorants and methylsalicylate. Polyvinylalcohol, polyvinylpyrrolidone, polyethylene glycol and xanthan gum can also be present.

[0014] The procedure followed to bind the starch and cellulose in stable form is to dilute the starch and cellulose in ethanol and water in a jacketed mixer then, while stirring, bringing them to a temperature of 80-90°C and maintaining them under stirring for at least 30 minutes to substantially eliminate the ethanol. Again while stirring, the mixture is brought again to a temperature around 30+35°C until a viscosity of 3+8000 mPas is obtained. The product obtained in this manner is able to retain considerable quantities of active substances, up to 30% by weight of its own weight: after evaporating all the residual water, active substance percentages between 10% and 50% by weight on the finished product are achieved. Moreover, once the mixture has cooled to 30+35°C and having lost its ethanol load, alcohol-sensitive substances such as lactic ferments, microorganisms or bacteria can be added to the mixture. This mixture is maintained under stirring and passed through a doctor blade assembly which does not compress the product and is able to distribute the product in the form of a thin film onto an antiadherent support which travels through a ventilated tunnel heated to 30+35°C to form the final film. This film is then separated from the anti-adherent support by known methods and die-cut into the required shape and size, then inserted into the final package.

EXAMPLE 1: The components of two separate phases known as "Phase A" and "Phase B" are used.

[0015] Phase A comprises:

H ₂ O	150 g
ethanol	150 g
hydroxypropylmethylcellulose	50 g
oxidized starch	20 g
polyvinyl alcohol	15 g
polyethylene glycol	4 g
glycerin	2 g
sorbitol	2 g
colorant	

Phase B comprises a mixture of aromatic essential oils (30 g) and aspartame (1 g).

[0016] The components of Phase A are fed into a jacketed closed mixer in the following succession: water, ethanol and oxidized starch are firstly fed and stirred at medium speed and the temperature brought to 80°C, stirring being continued until the starch has dissolved and caramelized, to obtain a homogeneous solution.

[0017] While stirring, the temperature is brought to 90°C and stirring maintained (at about 60 r.p.m.) for 30 minutes, then hydroxypropylmethylcellulose, polyethylene glycol and colorant are added and stirring continued until the solution is homogeneous.

[0018] It is cooled to 35°C, glycerol and sorbitol are added and stirring is maintained for 15 minutes. The temperature is brought to 30°C and

[0019] Phase B, previously mixed at ambient temperature, is slowly added. Stirring is maintained for 15 minutes. Using a peristaltic pump, the mixed product is withdrawn and made to flow onto a doctor blade assembly heated to 30°C, through which there passes a siliconized polyester web on which the product is deposited as a film to a thickness of 70 microns. The product (deposited as a film on polyester) is passed through a forced-air oven heated to 35°C. On leaving the oven the film is detached from the polyester support, and die-cut with a roller die into 2.3 x 3.3 cm rectangles,

(continued)

ethanol	150 g
hydroxypropylmethylcellulose	50 g
oxidized starch	40 g
carrageenan	10 g
polyethylene glycol 400 med	4 g
soya lecithin	10 g
methyl salicylate	1 g
colorant	

[0030] The components of Phase B are:

mixture of aromatic essential oils	40 g
aspartame	1 g

Phase A is fed into a jacketed closed mixer in the following manner: water, ethanol and oxidized starch, are firstly fed in, then stirred at medium speed and the temperature brought to 80°C, stirring then being continued until dissolution takes place to obtain a homogeneous solution.

[0031] While stirring, the temperature is brought to 90°C and stirring maintained for 30 minutes, then hydroxypropylmethylcellulose, carrageenan and colorant are added and stirring continued until the solution is homogeneous.

[0032] It is cooled to 35°C, polyethylene glycol 400 med, soya lecithin and methylsalicylate are added and stirring is maintained for 15 minutes. The temperature is brought to 30°C and Phase B, previously mixed at ambient temperature, is slowly added, and stirring is maintained for 15 minutes.

[0033] Using a peristaltic pump, the mixed product is withdrawn and made to flow onto a doctor blade assembly heated to 30°C, through which there passes a siliconized polyester support web on which the product is deposited as a film to a thickness of 70 microns. The product deposited as a film on the polyester web is passed through a forced-air oven heated to 35°C. On leaving the oven the film is detached from the polyester support, and die-cut with a roller die into 2.3 x 3.3 cm rectangles. The rectangles obtained are packaged in a hermetically sealed container.

[0034] Each rectangle obtained has a thickness of 33 microns, the time for its dissolving in the mouth being 5 seconds. The quantity of essential oils present is measured by HPLC, the result being the following:

weight of rectangle (2.3 x 3.3 cm)	26 mg
quantity of oils present	6.5 mg

EXAMPLE 4

[0035] Again a Phase A is used, comprising:

H ₂ O	150 g
ethanol	150 g
oxidized starch	60 g
hydroxypropylmethylcellulose	50 g
carrageenan	10 g
polyethylene glycol	4 g
glycerol	2 g
sorbitol	2 g
colorant	

together with a Phase B comprising food bacteria consisting of 100 g of lyophilized lactic ferments (lactobacillus paracasei).

[0036] Phase A is fed into a jacketed closed mixer in the following manner: water, ethanol and oxidized starch, are firstly fed in, then stirred at medium speed and the temperature brought to 80°C, stirring then being continued until the starch has dissolved to obtain a homogeneous solution.

[0037] While stirring, the temperature is brought to 90°C and stirring maintained for 30 minutes, then hydroxypro-



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EUROPEAN SEARCH REPORT

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The present search report has been drawn up for all claims			
Place of search MUNICH		Date of completion of the search 19 November 2003	Examiner Adechy, M
CATEGORY OF CITED DOCUMENTS X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document		T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document	

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ANNEX TO THE EUROPEAN SEARCH REPORT
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For more details about this annex : see Official Journal of the European Patent Office, No. 12/82